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Group III, claims 4 to 7, directed to methods of predicting susceptibility based on ARP1 nucleic acid molecules;

Group IV, claim 8, directed to a method of treatment based on ARP1 regulatory agents;

Group V, claims 9 to 11, directed to ARP2 nucleic acid molecules;

Group VI, claims 12 to 15, directed to diagnostic methods based on ARP2 nucleic acid molecules;

Group VII, claims 12 to 15, directed to methods of predicting susceptibility based on ARP2 nucleic acid molecules;

Group VIII, claim 16, directed to a method of treatment based on ARP2 regulatory agents;

Group IX, claims 17 to 19, directed to ARP3 nucleic acid molecules;

Group X, claims 20 to 23, directed to diagnostic methods based on ARP3 nucleic acid molecules;

Group XI, claims 20 to 23, directed to methods of predicting susceptibility based on ARP3 nucleic acid molecules;

Group XII, claims 24 to 26, directed to ARP3 polypeptides;

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Group XIII, claims 27 and 28, directed to an ARP3 binding agent;

Group XIV, claims 29 to 32, directed to diagnostic methods based on detecting ARP3 polypeptides;

Group XV, claims 29 to 32, directed to methods of predicting susceptibility based on detecting ARP3 polypeptides;

Group XVI, claim 33, directed to a method of treatment based on detecting ARP3 polypeptides;

Group XVII, claims 34 to 38, directed to ARP4 nucleic acid molecules;

Group XVIII, claims 39 to 42, directed to diagnostic methods based on ARP4 nucleic acid molecules;

Group XIX, claims 39 to 42, directed to methods of predicting susceptibility based on ARP4 nucleic acid molecules;

Group XX, claims 43 to 45, directed to ARP4 polypeptides;

Group XXI, claims 46 and 47, directed to an ARP4 binding agent;

Group XXII, claims 48 to 51, directed to diagnostic methods based on detecting ARP4 polypeptides;

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Group XXIII, claims 48 to 51, directed to methods of predicting susceptibility based on detecting ARP4 polypeptides;

Group XXIV, claim 52, directed to a method of treatment based on ARP4 regulatory agents;

Group XXV, claims 53 to 57, directed to ARP5 nucleic acid molecules;

Group XXVI, claims 58 to 61, directed to diagnostic methods based on ARP5 nucleic acid molecules;

Group XXVII, claims 58 to 61, directed to methods of predicting susceptibility based on ARP5 nucleic acid molecules;

Group XXVIII, claims 62 to 64, directed to ARP5 polypeptides;

Group XXIX, claims 65 and 66, directed to an ARP5 binding agent;

Group XXX, claims 67 to 70, directed to diagnostic methods based on detecting ARP5 polypeptides;

Group XXXI, claims 67 to 70, directed to methods of predicting susceptibility based on detecting ARP5 polypeptides;  
and

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Group XXXII, claim 71, drawn to a method of treatment based on ARP5 regulatory agents.

The Examiner additionally asserts that the methods of diagnosis and of predicting susceptibility to a prostate neoplastic condition include the following four patentably distinct species: prostate tissue, blood, urine and semen.

Applicant traverses the Restriction and Election of Species Requirements for the reasons stated below. Nevertheless, in order to be responsive to the Office Action, Applicant hereby elects with traverse the claims of Group XII (claims 24 to 26), which are directed to ARP3 polypeptides, for examination.

Regarding polypeptide claims and related methods

Applicant traverses the Restriction Requirement with respect to the restriction of the elected ARP3 polypeptide claims (Group XII) from the claims of Groups XIV and XV, directed to methods of diagnosing or predicting susceptibility to a prostate neoplastic condition by determining the expression levels of an ARP3 polypeptide. Applicant submits that, while the ARP3 polypeptides of Group XII are patentably distinct from the methods of Groups XIV and XV, search of the elected claims likely would uncover any art relevant to the methods of Groups XIV and XV. Furthermore, Applicant would remind the Examiner that a Restriction Requirement can only be proper if the following two requirements are met: (1) the inventions are independent or distinct; and (2) there is a serious burden on the Examiner. Where a serious burden does not exist, Restriction cannot be

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proper. In the present case, Applicant respectfully asserts that a search of the claims of Groups XII, XIV and XV together does not constitute such a "serious burden." In view of these remarks, Applicant respectfully requests that the Examiner reconsider the Restriction Requirement and examine the subject matter of Groups XIV and XV together with the elected subject matter of Group XII. For analogous reasons, Applicant traverses the Restriction Requirement with respect to the division of the claims of Group XX (ARP4 polypeptides) from Groups XXII and XXIII (methods based on determining the level of ARP4 polypeptide expression) and with respect to the division of the claims of Group XXVIII (ARP5 polypeptides) from Groups XXX and XXXI (methods based on determining the level of ARP5 polypeptide expression). Applicant appreciates the Examiner's reconsideration of the Restriction Requirement.

Regarding nucleic acid claims and related methods

Applicant further respectfully traverses the restriction of claims directed to nucleic acid molecules from methods based on the use of similar nucleic acid molecules. In particular, Applicant traverses the restriction of the claims of Group I (ARP1 nucleic acid molecules) from the claims of Groups II and III (methods based on the use of ARP1 nucleic acid molecules); restriction of the claims of Group V (ARP2 nucleic acid molecules) from the claims of Groups VI and VII (methods based on the use of ARP2 nucleic acid molecules); and further traverses the restriction of the claims of Group IX (ARP3 nucleic acid molecules) from the claims of Groups X and XI (methods based on the use of ARP3 nucleic acid molecules). Similarly, Applicant

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traverses the restriction of the claims of Group XVII (ARP4 nucleic acid molecules) from the claims of Groups XVIII and XIX (methods based on the use of ARP4 nucleic acid molecules); and restriction of the claims of Group XXV (ARP5 nucleic acid molecules) from the claims of Groups XXVI and XXVII (methods based on the use of ARP5 nucleic acid molecules). Again, while the nucleic acid composition claims are distinct from the nucleic acid molecule-based methods, a thorough search of the nucleic acid molecule compositions likely will uncover any art relevant to the related method claims. Applicant therefore asserts that search and examination of the nucleic acid molecule compositions and methods together does not constitute a serious burden on the Examiner.

Regarding methods of diagnosis and methods of predicting susceptibility

Applicant further respectfully traverses the restriction of methods of diagnosing a prostate neoplastic condition from methods of predicting susceptibility to a prostate neoplastic condition. Specifically, Applicant traverses restriction of the claims of Group II from Group III (methods relating to ARP1 nucleic acid molecules); restriction of the claims of Group VI from Group VII (methods relating to ARP2 nucleic acid molecules); restriction of the claims of Group X from Group XI (methods relating to ARP3 nucleic acid molecules); restriction of the claims of Group XIV from Group XV (methods relating to ARP3 polypeptides); restriction of the claims of Group XVIII from Group XIX (methods relating to ARP4 nucleic acid molecules); restriction of the claims of Group XXII from Group

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XXIII (methods relating to ARP4 polypeptides); restriction of the claims of Group XXVI from Group XXVII (methods relating to ARP5 nucleic acid molecules); and restriction of the claims of Group XXX from Group XXXI (methods relating to ARP5 polypeptides).

Applicant submits that, while each of these pairs of groups are patentably distinct, each pair of groups shares the same method steps and is classified in the same class and subclass. As an example, Groups II and III have the same method steps and are classified in class 435, subclass 6. In each of these pairs of claim groupings, the same or similar search would be performed for the first group of claims as for the second group; furthermore, any additional work involved in the search and examination of the first and second groups of claims together does not constitute a "serious burden" on the Examiner, especially in view of the fact that the claims have the same method steps. Applicant respectfully asks that this restriction be reconsidered.

Regarding the election of species requirement

Applicant further traverses the Election of Species Requirement requiring election of prostate tissue, blood, urine or semen. Applicant submits that, while methods practiced with prostate tissue, blood, urine or semen are patentably distinct, a thorough search of a method practiced with any one species likely would uncover any art relevant to the other species. Thus, the search and examination of the additional species would require only minimal work and would not constitute a serious burden.

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### III. CONCLUSION

Applicant appreciates the Examiner's reconsideration of the Restriction and Election of Species Requirements and further asks that the Examiner consider that rejoinder of the groups and species discussed above would eliminate duplicative work on the part of the Patent and Trademark Office. The Examiner is respectfully requested to call the undersigned agent if the Restriction Requirement is maintained in regard to the division of the claims of Group XII from the claims of Groups XIV and XV or if the Election of Species Requirement is maintained.

Respectfully submitted,

June 6, 2002  
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